Attorney Docket No.: 03-0226 (US01)

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/766,608 )
Examiner: Apanius Michael

Filed: January 27, 2004

For: SYSTEMS AND METHODS FOR TREATING BREAST TISSUE

## REPLY BRIEF-CFR 41.43

# MAIL STOP APPEAL BRIEF-PATENTS Commissioner for Patents

P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Brief is in reply to the Examiner's Answer dated August 20, 2007. Appellant agrees with the statements made in item numbers (1)-(8) of the Examiner's Answer, and respond to the statements made in item numbers (9) and (10) of the Examiner's Answer as follows:

# A. Rejection Under 35 U.S.C. §102(e) over Gatto

Appellant respectfully disagrees with the Examiner's reasoning for sustaining the rejection of claims 1, 7-9, 11, 15, 19, 20, 68-71, and 76-80 as being anticipated by Gatto.

The Examiner essentially argues that the tubes 46, 48 are eccentrically disposed within a cylindrical inner channel 43 defined by the outer cannula or sheath 42, and thus, the lumens 47, 49, although in a side-by-side relationship, are disposed within the

larger channel 43. Even assuming that this is true, however, Gatto does not disclose the combination of elements required by the claims. Notably, "the identical invention must be shown in as complete detail as is contained in the claims," and the "elements must be arranged as required by the claim . . . " (See MPEP §2131).

In this present case, the Fig. 6 embodiment of Gatto, which shows four side-byside lumens 47, 49, 52, 54 (resulting in the disposition of the tissue diagnostic device 12 and tissue treatment device 50 in separate lumens) is not arranged as required by independent claim 1 (i.e., the disposition of the tissue diagnostic device 12 and tissue treatment device 50 in the same lumen).

Applicant believes that the Examiner's reasoning is faulty, because the Examiner views the Gatto system from the perspective of a method of manufacture. That is, the sheath 42 is initially formed within a cylindrical channel 43, and then the tubes 46, 48 are disposed within the cylindrical channel 43. However, the claims are directed to a system—not a method of manufacturing the system. Thus, the Examiner must look at the resulting structure of the Gatto system—i.e., the combination of elements that make up the system. As clearly shown in Fig. 6, after the Gatto system is assembled, a cylindrical channel 43 no longer exists, but rather has been divided into two lumens 52, 54. Thus, the lumens 47, 49, 52, 54 are not disposed in the non-existent cylindrical channel 43.

## B. Rejection Under 35 U.S.C. §103(a) over Gatto and Hamm

Appellant respectfully disagrees with the Examiner's reasoning for sustaining the rejection of claims 2, 72, and 75 as being obvious over Gatto and Hamm, since Gatto does not disclose the combination of elements required by independent claim 1, as discussed above.

Attorney Docket No.: 03-0226 (US01)

#### C. Rejection Under 35 U.S.C. §103(a) over Gatto and Burbank

Appellant respectfully disagrees with the Examiner's reasoning for sustaining the rejection of claims 4, 16, 73, and 74 as being obvious over Gatto and Hamm.

The Examiner essentially argues that the act of removing suspect tissue in a biopsy is by itself a form a treatment. Applicant disagrees. It is highly doubtful that a physician, or a patient suspected of having breast cancer, would consider a biopsy a form of treatment.

Respectfully submitted,

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Dated: October 18, 2007

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